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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PACESETTER, INC.
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Sylmar, CA 91392-9221

EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/09/2004

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,854

Applicant(s)

DOAN ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis in the specification for the conductive coupling being cup shaped and having a base, a cylindrical side wall, and a bore; nor is there antecedent basis for the conductive stopper.

Claim Objections

2. Claim 10 is objected to because of the following informalities: “slidable reception *on* the conductive shaft”.

Claims 14 and 15 are objected to because of the following informalities: guide member and guide system are used interchangeably.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitations "the conductive shaft" in line 2, "the spiral track member" in line 5. The examiner suggests amending the claim to be dependent on claim 3, to provide proper antecedent basis.

Claim 10 recites the limitations "the conductive coupling" in line 2, "the conductive shaft" in line, "the compression spring" in line 8, "the conductive stopper" in line 9.

There is insufficient antecedent basis for these limitations in these claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Soukup (5,020,545).

Regarding claims 1-2, and 7, Soukup shows an electrically active housing comprising a tubular end region extending to a terminal rim at the distal end; an electrical conductor (38, 40); an active fixation electrode comprising a helix (82); and a guide system (78, 79, 94, 95, 180, 181, 182, 183) located proximally of the active fixation electrode (Figs. 1-7).

With respect to claim 3, Soukup shows a generally planar bulkhead member (66); a tubular end region (72); the guide system that further comprises a spiral track member (182, 183); and the active fixation electrode comprises a conductive shaft having an outer peripheral surface and having an outwardly projecting follower member (94, 95) slidably engaged with the spiral track member (Col. 8, lines 42-55; Fig. 7). For further clarification, the examiner considers the inward portions (facing the proximal end of the lead) of projections (66) at the terminal end of the lead to be the bulkhead, and the outer portion of the projections (66) that would be in contact with tissue to be the terminal rim, and the opening (72) to be the tubular end

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region extending away from the bulkhead member to the terminal rim at the distal end of the lead.

With respect to claim 4, Soukup shows an insulation sheath covering the electrical conductor, and an electrical connector (16, 18) coupled to the proximal end of the conductor (38, 40) (Col. 5, lines 3-14).

Regarding claim 12, Soukup further shows the electrically active housing comprises an electrically active collar (52) coaxial with the helix at the distal end of the lead (Fig. 1).

With respect to claim 13, Soukup further shows the electrically active helix (82) is fixed to the distal end of the conductive shaft (Fig. 1).

Regarding claims 14-15, Soukup further shows a cylindrical guide system integral with and extending proximally away from the bulkhead (66) and comprising a spiral track member (182, 183) and defined by opposed spaced parallel side walls and a bottom wall connecting the side walls (Fig. 7).

7. Claims 1-2, 4-5, 7, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rebell et al. (5,300,108).

Regarding claims 1-2, and 7, Rebell et al. shows an electrically active housing comprising a tubular end region extending to a terminal rim (34) at the distal end; an electrical conductor (25, 36); an active fixation electrode comprising a helix (15); and a guide system (10, 17, 18) (Figs. 2-3).

With respect to claim 4, Rebell et al. shows an insulation sheath (42) covering the electrical conductor, and an electrical connector (4) coupled to the proximal end of the conductor (6) (Figs. 1-3).

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Regarding claim 5, Rebell et al. shows a resilient coupling mechanism (17, 18) (Col. 10, lines 10-15).

Regarding claim 12, Rebell et al. further shows the electrically active housing comprises an electrically active collar (12) coaxial with the helix at the distal end of the lead (Figs. 2-3).

With respect to claim 13, Rebell et al. further shows the electrically active helix (82) is fixed to the distal end of the conductive shaft (25) (Fig. 2).

8. Claims 1-2, 4-5, 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Doan (6,687,550).

Regarding claims 1-2, and 7, Doan shows an electrically active housing comprising a tubular end region extending to a terminal rim (108) at the distal end; an electrical conductor (92, 120, 124,); an active fixation electrode comprising a helix (102); and a guide system (138) (Figs. 4-5).

With respect to claim 4, Doan shows an insulation sheath (109) covering the electrical conductor, and an electrical connector (28) coupled to the proximal end of the conductor (92) (Figs. 1, 4-5).

Regarding claim 5, Doan shows a resilient coupling mechanism (110).

With respect to claims 8-9, Doan et al. shows a therapeutic element (146) integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue (Figs. 1, 4-5).

Regarding claims 10-11, Doan shows a cup shaped conductive coupling (128) comprising a base lying in a plane transverse to the longitudinal axis of the conductive shaft, and a

cylindrical sidewall upstanding from the base and coaxial with the longitudinal axis of the conductive shaft (112), the base having a bore for slidable reception of the conductive shaft, and a compression spring (144) that extends between the base and a conductive stopper (140) (Col. 5, lines 24-36, Figs. 1, 4-5).

With respect to claim 12, Doan further shows the electrically active housing comprises an electrically active collar (106) coaxial with the helix at the distal end of the lead (Figs. 1, 4-5).

Regarding claim 13, Doan further shows the electrically active helix (102) is fixed to the distal end of the conductive shaft (Figs. 1, 4-5).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup (5,020,545) in view of Vachon et al. (5,447,533). Soukup is as explained before. Although Soukup fails to teach a therapeutic element integral with the active fixation electrode, generally

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cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue, attention is directed to Vachon et al. which shows a lead with a therapeutic element (62) having these characteristics. Vachon teaches that it is highly desirable to have an a therapeutic element that is capable of penetrating the myocardial wall because therapeutic material eluted from the surface of the electrodes of prior art leads would be washed away by blood pumping through the heart (Col. 2, line 39- Col. 3, line17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the lead of Soukup to include a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue as Vachon et al. teaches in order to avoid the therapeutic material from being washed away by blood pumping through the heart.

11. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rebell et al. (5,300,108) in view of Vachon et al. (5,447,533). Rebell et al. is as explained before. Although Rebell et al. fails to teach a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue, attention is directed to Vachon et al. which shows a lead with a therapeutic element (62) having these characteristics. Vachon teaches that it is highly desirable to have an a therapeutic element that is capable of penetrating the myocardial wall because therapeutic material eluted from the surface of the electrodes of prior art leads would be washed away by blood pumping through the heart (Col. 2, line 39- Col. 3, line17). Therefore, it would have been obvious to one with ordinary skill

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in the art at the time the invention was made to modify the lead of Rebell et al. to include a therapeutic element integral with the active fixation electrode, generally cylindrical in shape and coaxial with and fixed on the distal end of the conductor and formed of a matrix material of sufficient rigidity to penetrate myocardial tissue as Vachon et al. teaches in order to avoid the therapeutic material from being washed away by blood pumping through the heart.

Allowable Subject Matter

12. Claim 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim (2) and any intervening claims (3).

The prior art of record fails to teach or suggest a lead with an active fixation electrode having a conductive shaft with a outwardly projecting follower member slidably engaged with a spiral track member of an electrically conductive housing, an annular collar integral with the conductive shaft projecting radially from the longitudinal axis to an outer rim beyond the outer surface of the conductive shaft, a head portion coaxial with and extending distally from the annular collar and having a diameter smaller than the annular collar defining a distal annular shoulder; and a compression spring engaged between a planar bulkhead member of the conductive housing and the distal annular shoulder, where the annular collar and distal annular shoulder are located proximal from the bulkhead member.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grassi (4,624,265) and Flynn et al. (6,463,334) each show leads with extendable and retractable helix electrodes each lead having spiral guide members.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

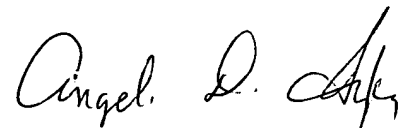
The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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